



高雄醫學大學附設中和紀念醫院
Kaohsiung Medical University Chung-Ho Memorial Hospital
人體試驗審查委員會
Institutional Review Board

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人體研究新案同意證明書

計畫中文名稱：腫瘤第4期之大腸直腸癌病患接受化學放射治療及開刀後之預後

計畫主持人：黃鈞民

共同及協同主持人：王照元、黃旼儀

機構名稱：高雄醫學大學附設中和紀念醫院

經費來源：自籌、科技部

IRB 編號：KMUHIRB-E(II)-20190281

核准日期：2019年10月28日

計畫執行期間：自2019年10月28日至2020年7月31日止

本同意書有效期限：至西元2020年10月27日止

計畫書：第一版，2019年10月28日

免除知情同意申請書：第一版，2019年8月22日

未預期事件或藥品嚴重不良反應通報、後續定期追蹤之程序及應注意事項，請參閱背面。



高雄醫學大學附設中和紀念醫院
第二人體試驗審查委員會
主任委員：賴秋蓮



西 元 2 0 1 9 年 1 0 月 2 8 日

Approval of Clinical Trial/Research

Protocol Title: *Oncologic outcomes of neoadjuvant chemoradiation therapy followed by radical resection for patients with T4 colorectal cancer*

Principal Investigator(s): Chun-Ming Huang

Co_Investigator(s): Jaw-Yuan Wang, Ming-Yii Huang,

Institution: Kaohsiung Medical University Chung-Ho Memorial Hospital

Source of Funding: Self-financing, Ministry Of Science and Technology

IRB Number: KMUHIRB-E(II)-20190281

Approval dated: 2019/10/28

Duration of Approval: from 2019/10/28 to 2020/7/31

An interim report : 2020/10/27.

Protocol : Version 1, 2019/10/28

Waiver of Informed Consent Form : Version 1, 2019/8/22

See the back of this page for the procedures for reporting unanticipated problems, or drug serious adverse reactions, or interim, and other important notes.

Chiou-Lian Lai

Chiou-Lian Lai, MD

Chairman

Institutional Review Board-II

Kaohsiung Medical University

Chung-Ho Memorial Hospital



未預期事件通報、後續定期追蹤之程序及應注意事項

本會組織與執行皆符合 ICH-GCP

The Institutional Review Board performs its functions according to written
Operating procedures and complies with ICH-GCP and with the applicable regulations.

1. 院內受試者發生死亡或危及生命案例應該在獲知日起七日以內通報本委員會，其他非預期嚴重藥品不良反應應於十五日以內向本委員會通報。
2. 可能危害受試者安全、影響試驗執行之新發現或影響人體試驗委員會同意試驗繼續進行之新發現，須向本委員會報告。
3. 請於本同意書有效期限到期二個月內繳交持續審查報告至本會審查。有效期限屆滿，若尚未通過持續審查報告追蹤審查，不得繼續試驗。計畫主持人，未依規定繳交持續審查報告，本會得暫停審查受理中的計劃文件，且不受理其新申請案。
4. 結案報告：試驗完成後，應將執行情形及結果以書面報告本會核備。
5. 提前中止或終止計畫報告：計畫完成前就提前中止或停止收案與追蹤，應與書面「計畫提前中止或終止摘要表」，送交本會核備。
6. 嚴重或持續不配合本委員會規範，未能遵循以上事項，可能導致您的研究計畫提前中止或永久終止，並影響您未來送審計畫的權益。

Procedures for reporting Unanticipated Problems , or interim, and other important notes:

1. If subject(s) die(s) or hospitalized, IRB should be notified within 7 days of becoming aware of this. For other unexpected serious adverse drug reactions, IRB should be notified within 15 days.
2. If any new findings affect the safety of the participants or others, or the implementation of the study or decision of IRB as to allow to continuing of the study, IRB should be informed promptly.
3. Please provide us your Interim report two months before the dead line of ***Duration of Approval***. If the interim report has not been submitted by the deadline, the study must be halted. If a principal investigator fails to submit an interim report on schedule, IRB may suspend review of other protocols submitted by the investigator, and may refuse to review any further applications made by the investigator.
4. Final report: When the study has been completed, details of the study implementation and of the results obtained should be submitted to IRB in writing for review.
5. For any reason, the study is terminated prior to the completion of a study. The summary report should be submitted to IRB.
6. Serious or repeated failure to comply with regulations and with the above requirements may result in the study being suspended or terminated, and may affect you to submit studies for review in the future.